

General Information

201-14950B

CAS Number: 102-71-6
Common Name: Triethanolamine

II. Physical-Chemical Data

A. Melting Point

Test Substance

Identity: Triethanolamine
Remarks: None

Method

Method: Not stated.
GLP: No
Remarks: None

Results

Melting Point Value: 21°C
Remarks: None

Conclusions

The melting point was provided by a reliable resource. The endpoint has been adequately characterized.

Data Quality

Reliability: 2D
Remarks: Reliable with restrictions; endpoint was provided in a reliable reference text.

Reference

Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

Other

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B. Boiling Point

Test Substance

Identity: Triethanolamine
Purity: Not stated
Remarks: None

Method

Method: Not stated
GLP: No
Year: Not stated
Remarks: None

Results

Boiling Point Value: 335°C
Remarks: None

Conclusions

The boiling point was provided in a reliable resource book. The endpoint has been adequately characterized.

Data Quality

Reliability: 2D
Remarks: Reliable with restrictions; endpoint was provided in a reliable reference text.

Reference

Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

Other

C. Vapor Pressure

Test Substance

Identity: Triethanolamine
Remarks: None

Method

Method: Measured
GLP: No
Remarks: None

Results

Vapor Pressure Value: 0.000477 Pa at 25°C
Remarks: None

Data Quality

Reliability: 2D
Remarks: Reliable with restrictions; endpoint was provided in a reliable reference text.

Reference

Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

Other

D. Partition Coefficient – Entry 1 of 3

Test Substance

Identity: Triethanolamine
Remarks: None

Method

Method: Inkrementenmethode von Rekker mit
Computerprogram der Firma CompuDrug Ltd.
GLP: Not stated
Remarks: None

Results

Log K_{ow} : -2.53
Remarks: None

Data Quality

Reliability: 2D
Remarks: Reliable with restrictions.

Reference

BASF AG. Labor fuer Umweltanalytik;
unveroeffentlichte Untersuchung. 1989.

Other

Entry 2 of 3 for Partition Coefficient

Test Substance

Identity: Triethanolamine
Purity: Not stated
Remarks: None

Method

Method: OECD Guideline 107 – Partition Coefficient (n-octanol/water), Flask shaking method.
GLP: Not stated
Year: 1991
Remarks: None

Results

Log K_{ow} : -2.3
Temperature: 25°C
Remarks: None

Data Quality:

Reliability: 1A.
Remarks: Reliable without restrictions; Guideline study.

Reference

BASF AG. Analytisches Labor; unveroeffentlichte Untersuchung (J. Nr. 90P03095.03 vom 05.04.1991)

Other

Entry 3 of 3 for Partition Coefficient

Test Substance

Identity: Triethanolamine
Purity: Not stated
Remarks: None

Method

Method: Not stated
GLP: Not stated
Year: 1990
Remarks: None

Results

Log K_{ow} : -1.59
Temperature: 20°C
Remarks: None

Data Quality:

Reliability: 2D
Remarks: Reliable with restrictions. Endpoint was provided in a reliable reference text.

Reference

Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

Other

E. Water Solubility

Test Substance

Identity: Triethanolamine
Remarks: None

Method

Method: Not stated
GLP: Not stated
Remarks: None

Results

Value: Miscible
Temperature: 25°C
Remarks: None

Data Quality:

Reliability: 2D
Remarks: Reliable with restrictions. Endpoint was provided in a reliable reference text.

Reference

Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

Other

III. Environmental Fate Endpoints

A. Photodegradation – Entry 1 of 2

Test Substance

Identity: Triethanolamine
Remarks: None

Method

Method: Other (calculated)
GLP: Not stated
Remarks: None

Results

Hydroxyl radicals
reaction:
OH Rate
Constant: $1.04 \text{ E-}12 \text{ cm}^3/\text{molecule-sec}$
Degradation: 50% after 4 hours
Ozone reaction: No ozone reaction estimation
Remarks: None

Data Quality:

Reliability: 2D
Remarks: Reliable with restrictions. Endpoint was provided in a reliable reference text.

Reference

Atkinson, R. Inter. J. Chem. Knot 19: 799-828.
1987. Listed in: Howard, P. H. Handbook of
Environmental Fate and Exposure Data for Organic
Compounds. Lewis Publishers. 1990.

Other

Entry 2 of 2 for Photodegradation

Test Substance

Identity: Triethanolamine
Remarks: None

Method

Method: Estimation
Model: Atmospheric oxidation
Remarks: None

Results

Hydroxyl radicals
reaction:
OH Rate
Constant: 110 E-12 cm³/molecule-sec
Half-Life: 1.16 hours
Ozone reaction: No ozone reaction estimation
Remarks: None

Data Quality:

Reliability: 2D
Remarks: Reliable with restrictions. Endpoint was provided
by computer modeling.

Reference:

AopWin v.1.90. (EPI SuiteTM v.3.10).
Downloadable at
[http://www.epa.gov/oppt/exposure/docs/episuitedl.h
tm](http://www.epa.gov/oppt/exposure/docs/episuitedl.htm). ©2000 U. S. Environmental Protection Agency.

B. Stability in Water

Test Substance

Identity:

Triethanolamine

Remarks:

If released to water, Triethanolamine should biodegrade. The half-life of this compound is expected to range from a few days to a few weeks depending on the degree of acclimation of the system. Bioconcentration in aquatic organisms, adsorption to suspended solids and sediments, and volatilization are not expected to be important fate processes in water. Triethanolamine does not decompose or hydrolyze in contact with water and there is no abiotic degradation.

Reference

Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

C. Biodegradation – Entry 1 of 2

Test Substance

Identity: Triethanolamine
Purity: Not stated
Remarks: None

Method

Method: OECD Guideline 302B “Inherent biodegradability:
Modified Zahn-Wellens Test”
Test type: Aerobic
GLP: Not stated
Year: 1979
Contact time: 8 days
Inoculum: Activated sludge
Concentration: 400 mg/l
Remarks: None

Results

Degradation: 82% after 8 days
Results: Inherently biodegradable
Remarks: None

Conclusions

The biodegradability of the test substance has been adequately characterized.

Data Quality

Reliability: 1A
Remarks: Reliable without restrictions; OECD guideline study.

Reference

Gerike, P., Fischer, W. K. 1979. A Correlation Study of Biodegradability Determinations with Various Chemicals in Various Tests. ECETOX. Environ. Safety. 3: 159-173.

Other

Entry 2 of 2 for Biodegradation

Test Substance

Identity: Triethanolamine
Purity: Not stated
Remarks: None

Method

Method: OECD Guideline 302 B
Test type: Aerobic
GLP: Not stated
Year: 1980
Contact time: 14 days
Concentration: 1000 mg/l
Inoculum: Domestic sewage
Remarks: None

Results

Degradation: 89 % after 14 days
Results: Inherently biodegradable
Kinetic: Not stated
Breakdown products: Not stated
Remarks: None

Conclusions

The biodegradability of the test substance has been adequately characterized.

Data Quality

Reliability: 1A
Remarks: Reliable without restrictions; OECD guideline study.

Reference

Zahn, R. and Wellens, H. 1980. Examination of Biological Degradability through the Batch method – further Experience and New Possibilities of Usage. Z. Wasser Abwasser Forsch. 13: 1-7.

Other

D. Transport between Environmental Compartments (Fugacity)

Test Substance

Identity: Triethanolamine
Remarks: None

Method

Method: Calculation according to Mackay, Level I
Remarks: Data used:
Molecular mass: 149.2
Log₁₀ octanol/water partition coefficient: -1.59
Water solubility: 10,000 mg/l (As triethanolamine is fully miscible with water, an estimated value as shown was used.)
Vapor pressure: 0.000477 Pa at 25°C
Amount of chemical dispersed: 10 moles

Results

Distribution to each medium	Percent Distribution
Air	<0.001
Water	99.999
Soil	<0.001
Sediment	<0.001

Remarks: None

Reference

Comber, M. I. H. Zeneca Brixham Environmental Laboratory. Letter to M. G. Penman. ICI Chemicals & Polymers Limited. 1993.

Other

IV. Ecotoxicity

A. Acute Toxicity to Fish – Entry 1 of 2

Test Substance

Identity: Triethanolamine
Purity: Not stated
Remarks: None

Method

Method: Static
Test type: 24-hour LC₅₀
Analytical monitoring: No data
Organism: *Carassius auratus* (goldfish, freshwater species)
Year: 1979
GLP: No data
Statistical methods: None
Remarks: The test procedure was in accordance with American Public Health Association guideline. Goldfish of uniform length (average 6.2±0.7 cm) and weight (average 3.3 g) and in good health were used for the assay. Triethanolamine was tested at a series of concentrations. In each test 10 fish were exposed in 25 liters of solution (pH – 9.9; temperature – 20°C) contained in all glass tanks. The solutions were aerated throughout the test period.

Results

LC₅₀ (24 hours): > 5000 mg/l
Remarks: None

Conclusion

The acute toxicity of the test substance has been adequately characterized.

Data Quality

Reliability: 2A
Remarks: Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles.

Reference

Birdie, A. L., C. J. M. Wolff and M. Winter. 1979. The Acute Toxicity of Some Petrochemicals to Goldfish. Water Res. 13: 623-626.

Other

Entry 2 of 2 – Acute Toxicity to Fish

Test Substance

Identity: Triethanolamine
Purity: 97 %
Remarks: None

Method

Method: Not stated
Test type: Acute
GLP: No data
Year: 1987
Species: *Pimephales promelas*
Analytical monitoring: Yes
Exposure period: 96 hours
Statistical methods: None
Remarks: The conditions of the test solutions were as follows: pH – 7.8; temperature – 25.7°C; dissolved oxygen – 7.3 mg/l.

Results

LC₅₀ (96 hours): 11,800 mg/l
Remarks: The affected fish lost schooling behavior, were hyperactive and darkly colored, had increased respiration and lost equilibrium prior to death.

Conclusion

The acute toxicity of the test substance has been adequately characterized.

Data Quality

Reliability: 2A
Remarks: Reliable with restriction; Acceptable, well-documented publication report which meets basic scientific principles.

Reference

Geiger, D. L., L. T. Brooks and D. J. Call. Acute Toxicities for Organic chemicals to Fathead Minnows (*Pimephales promelas*). Volume V. Center for lake Superior Environmental Studies, University of Wisconsin – Superior. 1984-88.

Other

B. Acute Toxicity to Daphnids – Entry 1 of 2

Test Substance

Identity: Triethanolamine
Purity: Not stated
Remarks: None

Method

Method: DIN 38412 part 11
Test type: Acute static
GLP: No data
Year: 1982
Species: *Daphnia magna*
Analytical monitoring: No
Exposure period: 24 hours
Statistical methods: No statistics applied to data
Remarks: Test medium was not neutralized. Concentrations were nominal.

Results

EC₅₀ (24 hours): 1386 mg/l
EC₁₀₀ (24 hours): 2455 mg/l

Conclusions

The 24-hour acute toxicity of the test substance to *Daphnia magna* has been adequately characterized.

Data Quality

Reliability: 2A
Remarks: Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles.

Reference

Bringmann, G. and R. Kuhn. 1982. Z. Wasser Abwasser Forsch. 15: 6-11.

Other

Acute Toxicity to Daphnids – Entry 2 of 2

Test Substance

Identity: Triethanolamine
Purity: Not stated
Remarks: None

Method

Method: Not stated
Test type: Acute static
GLP: No data
Year: 1987
Species: *Daphnia magna*
Analytical monitoring: No
Exposure period: 24 hours
Statistical methods: No statistics applied to data
Remarks: Test was conducted at pH 7.6-7.7 and 20-22°C.

Results

EC₅₀ (24 hours): 1390 mg/l

Conclusions

The 24-hour acute toxicity of the test substance to *Daphnia magna* has been adequately characterized.

Data Quality

Reliability: 2A
Remarks: Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles.

Reference

Bringmann, G. and R. Kuehn. 1987. Results of the damaging effect of water pollutants on *Daphnia magna*. Z. Wasser Abwasser Forsch. 20: 161-166.

Other

C. Acute Toxicity to Aquatic Plants (Algae) – Entry 1 of 2

Test Substance

Identity: Triethanolamine
Purity: Not stated
Remarks: None

Method

Method: DIN 38412, Part 9
Test type: Acute static growth inhibition
GLP: Not stated
Year: 1986
Species: *Scenedesmus subspicatus*
Analytical monitoring: No
Exposure period: 96 hours
Statistical methods: No statistics applied to data
Remarks: The assay was conducted with and without neutralized triethanolamine. Concentrations were nominal.

Results

	Neutralized	Non-neutralized
EC ₁₀ :	13.2 mg/l	7.1 mg/l
EC ₅₀ :	910 mg/l	169 mg/l
EC ₉₀ :	62,500 mg/l	4030 mg/l

Conclusions

The 96-hour acute toxicity of the test substance to *Scenedesmus subspicatus* has been adequately characterized.

Data Quality

Reliability: 2A
Remarks: Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles.

Reference

Amann, W. and A. Stainhauser. 1986.
Umweltforschungsplan des BMI, UFOPLAN Nr.
102 05 308. im Auftrag des Umweltbundesamtes.

Other

Entry 2 of 2 – Acute Toxicity to Aquatic Plants (Algae) –

Test Substance

Identity: Triethanolamine
Purity: Not stated
Remarks: None

Method

Method: DIN 38412, Part 9
Test type: Acute static growth inhibition
GLP: Not stated
Year: 1990
Species: *Scenedesmus subspicatus*
Analytical monitoring: No
Exposure period: 72 hours
Statistical methods: No statistics applied to data
Remarks: None

Results

EC₁₀: 110 mg/l
EC₅₀: 750 mg/l

Conclusions

The 72-hour acute toxicity of the test substance to *Scenedesmus subspicatus* has been adequately characterized.

Data Quality

Reliability: 2A
Remarks: Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles.

Reference

Kuhn, R. and M. Pattard. 1990. Results of the Harmful Effects of Water Pollutants to Green Algae (*Scenedesmus subspicatus*) in the Cell Multiplication Inhibition Test. Water. Res. 24: 31-38.

Other

V. Mammalian Toxicity

A. Acute Toxicity – Entry 1 of 5

Test Substance

Identity: Triethanolamine
Purity: 91.8 % triethanolamine; 6.1 % diethanolamine
Remarks: None

Method

Method/guideline followed: Not stated
Type: Oral toxicity
GLP: No data
Year: 1973
Species/Strain: Rat/strain not stated
Sex: Male/Female
Number of animals/sex/dose: 5
Vehicle: Not stated
Route of administration: Oral (gavage)
Remarks: Five dose groups of 10 rats each were administered the test substance between 3.64 and 10.0 g/kg. Animals were observed for mortality and clinical signs for 14 days.

Results

Value: LD₅₀ is 7.39 g/kg
Mortality rate: Not stated
Remarks: There was slight to moderate degrees of hemorrhagic rhinitis in rats administered doses equal to or greater than 7.14 g/kg.

Conclusions

Remarks: The acute oral LD₅₀ is 7.39 g/kg.

Data Quality

Reliability: 2D
Remarks: The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study.

Reference

Cosmetic Ingredient Review. 1983. Final Report on the Safety Assessment of Triethanolamine,

Diethanolamine and Monoethanolamine. J. Am.
Coll. Toxicol. 2 (7): 173-235.

Acute Toxicity – Entry 2 of 5

Test Substance

Identity: Triethanolamine
Purity: Purity not stated
Remarks: None

Method

Method/guideline followed: Not stated
Type: Oral toxicity
GLP: No data
Year: 1951
Species/Strain: Rat/strain not stated
Sex: Males
Number of animals/sex/dose: 6 animals/dose
Vehicle: Water
Route of administration: Oral (gavage)
Remarks: None

Results

Value: LD₅₀ is 9.11 g/kg
Mortality rate: Not stated
Remarks: No clinical information given.

Conclusions

Remarks: The acute oral LD₅₀ is 9.11 g/kg.

Data Quality

Reliability: 2D
Remarks: The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study.

Reference

Smyth, H. F., Carpenter, C. P. and Weil, C. S. 1951. Range-finding toxicity data: List IV. Arc. Ind. Hyg. Occ. Med. 4: 119-22.

Acute Toxicity – Entry 3 of 5

Test Substance

Identity: Triethanolamine
Purity: Commercial grade
Remarks: None

Method

Method/guideline followed: Not stated
Type: Oral toxicity
GLP: No data
Year: 1940
Species/Strain: Rat/strain not stated
Sex: Not stated
Number of animals/sex/dose: 10 animals/dose
Vehicle: Test article was administered undiluted.
Route of administration: Oral (gavage)
Dose range: 1 to 12 g/kg
Remarks: None

Results

Value: LD₅₀ is 8 g/kg
Mortality rate: Not stated
Remarks: The average survival time after administration was 24 hours. The author states that mortality was probably the result of the alkalinity of the material. The gross pathological change was confined to the gastrointestinal tract. The stomach was distended, congested and showed hemorrhagic areas. The blood vessels of the large and small intestines were distended. Liver, kidney, spleen and lungs showed no gross pathological changes. Before death, most of the animals had an intense diarrhea and were completely prostrate.

Conclusions

Remarks: The acute oral LD₅₀ is 8 g/kg.

Data Quality

Reliability: 2D
Remarks: The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study.

Reference

Kindsvatter, V. H. 1940. Acute and chronic toxicity of triethanolamine. *J. Indus. Hyg. Toxicol.* 22 (6): 206-212.

Acute Toxicity – Entry 4 of 5

Test Substance

Identity: Triethanolamine
Purity: Purity not stated
Remarks: None

Method

Method/guideline followed: Per method used for inhalation toxicity at BASF
Type: Inhalation toxicity
GLP: No
Year: 1966
Species/Strain: Rat/strain not stated
Sex: Not stated
Number of animals/sex/dose: Not stated
Vehicle: None
Route of administration: Inhalation
Remarks: The animals were exposed to a saturated atmosphere of triethanolamine for 8 hours at 20° C.

Results

Value: LC₅₀ is greater than a saturated atmosphere.
Mortality rate: No mortality.
Remarks: No clinical information given.

Conclusions

Remarks: The acute inhalation LC₅₀ is greater than a saturated atmosphere.

Data Quality

Reliability: 2D
Remarks: The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study.

Reference

BASF AG. 1966 Abteilung Toxikologie.
Unpublished report. ZST-Nr. SV/307.

Acute Toxicity – Entry 5 of 5

Test Substance

Identity: Triethanolamine
Purity: 91.8 % triethanolamine; 6% diethanolamine
Remarks: None

Method

Method/guideline followed: Not stated
Type: Dermal toxicity
GLP: No
Year: 1973
Species/Strain: Rat/strain not stated
Sex: Not stated
Number of animals/sex/dose: Not stated
Vehicle: None
Route of administration: Dermal
Remarks: None

Results

Value: LD₅₀ is greater than 2 g/kg
Mortality rate: None
Remarks: No clinical information given.

Conclusions

Remarks: The acute dermal LD₅₀ is greater than 2 g/kg.

Data Quality

Reliability: 2D
Remarks: The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study.

Reference

Cosmetic Ingredient Review. 1983. Final Report on the Safety Assessment of Triethanolamine, Diethanolamine and Monoethanolamine. J. Am. Coll. Toxicol. 2 (7): 173-235.

B. Genetic Toxicity – Entry 1 of 3

Test Substance

Identity: Triethanolamine
Purity: Reported as reagent grade
Remarks: None

Method

Method: Ames/*Salmonella* Bacterial Point Mutation Assay
Type: Reverse mutation assay
Test system: Bacteria
GLP: Not stated
Year: 1982
Species/Strain: *Salmonella typhimurium*/TA98 and TA100.
Metabolic activation: Test conducted with and without metabolic activation.

Concentrations

tested: 0 to 20,000 µg/plate

Remarks: Triethanolamine was dissolved in 0.1 ml of distilled water and added to 0.5 ml of S9 mix or 0.1 M sodium phosphate buffer (pH 7.4) with 0.1 ml of bacterial culture. The mixtures were incubated for 20 minutes at 37° C with shaking. It was then mixed rapidly with 2 ml of molten soft agar containing 0.1 µmole of L-histidine and biotin, poured onto minimal glucose agar plates and incubated for 2 days at 37° C. S9 mix was prepared from the post-mitochondrial supernatant of the liver of rats that had been pretreated with polychlorinated biphenyl for induction of microsomal enzymes. Concurrent solvent (water) and positive controls (without activation – 4-nitroquinoline 1-oxide; with activation – benzo[a]pyrene) were tested with and without the metabolic activation systems.

Results

There was no difference between controls and all concentrations tested in revertant colonies/plate with or without metabolic activation.

Conclusions

Remarks: The test substance did not induce mutations in this test system with and without metabolic activation.

Data Quality

Reliability: 1B

Remarks: Reliable without restriction; comparable to guideline study.

Reference

Inoue, K., T. Sunakawa, K. Okamoto and Y. Tanaka. 1982. Mutagenicity tests and in vitro transformation assays on triethanolamine. *Mut. Res.* 101: 305-313.

Other

Genetic Toxicity – Entry 2 of 3

Test Substance

Identity: Triethanolamine
Purity: Reported as practical grade
Remarks: None

Method

Method: Ames/*Salmonella* Bacterial Point Mutation Assay
Type: Reverse mutation assay
Test system: Bacteria
GLP: Not stated
Year: 1986
Species/Strain: *Salmonella typhimurium*/TA98, TA100, TA 1535 and TA 1537.
Metabolic activation: Test conducted with and without metabolic activation.

Concentrations

tested: 0 to 3,333 µg/plate

Remarks: Male Sprague-Dawley rats were used to prepare the S-9 fraction. Liver microsomal enzymes were induced with polychlorinated biphenyl (Arochlor 1254). The S-9 mix was prepared immediately prior to the assay and consisted of the following per ml: 0.04 M β-nicotinamide adenine dinucleotide phosphate, 0.10 ml; 0.05 M glucose-6-phosphate, 0.10 ml; 1.0 M NaH₂PO₄, pH 7.4, 0.10 ml; and distilled water, 0.56 ml. Triethanolamine was assayed in the preincubation assay. To each test tube maintained at 37° C was added in the following order: 0.5 ml of S-9 mix or 0.1 M PO₄ buffer (pH 7.4), 0.05 ml of the overnight culture, and 0.05 ml of solvent or chemical dilution. The mixture was mixed and allowed to incubate without shaking at 37° C for 20 minutes, at which time 2.0 ml of molten top agar supplemented with 0.5 mM L-histidine and 0.5 mM D-biotin were added. The contents of the tubes were mixed and pured onto 25 ml of minimal glucose bottom agar in 15 x 100-mm plastic petri dishes. When the top agar has solidified, the plates were nverted and incubated at 37° C for 48 hours. Concurrent solvent (water) and positive controls (without activation – sodium azide for TA 1535 and TA 100, 4-nitro-o-phenylenediamine for TA 98, 9-aminoacridine for TA 1537; with activation – 2-aminoanthracene for

all strains) were tested with and without the metabolic activation systems.

Results

There was no difference between controls and all concentrations tested in revertant colonies/plate with or without metabolic activation.

Conclusions

Remarks:

The test substance did not induce mutations in this test system with and without metabolic activation.

Data Quality

Reliability:

1B

Remarks:

Reliable without restriction; comparable to guideline study.

Reference

Mortelmans, K., S. Haworth, T. Lawlor, W. Speck, B. Tainer and E. Zeiger. 1986. *Salmonella* Mutagenicity Tests: II. Results from the Testing of 270 Chemicals. Environ. Mut. 8, Supplement 7: 1-119.

Other

Genetic Toxicity – Entry 3 of 3

Test Substance

Identity: Triethanolamine
Purity: Reported as reagent grade
Remarks: None

Method

Method: That of Ishidate and Odashima (1977) as reported in Mutation Research 48: 337-354.

Type: Cytogenetic assay

Test system: Chinese hamster lung cells

GLP: Not stated

Year: 1982

Species/Strain: CHL cells

Concentrations tested: 0 to 100 µg/ml

Remarks: Inocula of 2×10^4 CHL cells suspended in Eagle's MEM supplemented with 10% fetal calf serum were seeded into 60-mm petri dishes. After cultivation for 3 days, a test chemical was then added and incubation was continued for 24 or 48 hours. Colcemid was added to the media at a final concentration of 0.2 µg/ml for the last 2 hours of incubation. After trypsinization, the cells were incubated in hypotonic solution (0.075-M KCl) for 15 minutes at 37° C. The cells were then fixed with ice-cold fixative (methanol:glacial acetic acid, 3:1) with 3 changes of the solution. A few drops of the cell suspension were placed on a slide on wet blotting paper, and the slide was stained with Giemsa. At each concentration of the chemical, 100 metaphase cells were examined for chromosomal aberrations. The controls consisted of a tissue culture control, vehicle control (DMSO) and a positive control (N-methyl-N'-nitro-N-nitrosoguanidine).

Results

There was no difference between controls and all concentrations tested in chromatid gaps, chromatid breaks, chromatid exchanges or number of polyploid cells.

Conclusions

Remarks: The test substance did not induce chromosome aberrations in this test system with and without metabolic activation.

Data Quality

Reliability: 1B

Remarks: Reliable without restriction; comparable to guideline study.

Reference

Inoue, K., T. Sunakawa, K. Okamoto and Y. Tanaka. 1982. Mutagenicity tests and in vitro transformation assays on triethanolamine. *Mut. Res.* 101: 305-313.

Other

C. Repeated Dose Toxicity – Entry 1 of 2

Test Substance

Identity: Triethanolamine
Purity: 88.5 % triethanolamine and 6 % diethanolamine
Remarks: None

Method

Method/guideline followed: Not stated
Test type: Oral
Year: 1976
GLP: No data
Species: Rat
Strain: Not stated
Number and sex: 20 males and 20 females/group. Animals were exposed to 4 dose levels ranging from 0 to 1000 mg/kg.
Route of administration: Oral (incorporation into the feed)
Duration of test: 91 days
Control group and treatment: No information on control group specified
Post-exposure observation period: Not specified
Methods: Animals were dosed for 91 days and then evaluated for hematologic effects and pathological change.

Results

NOAEL: 1000 mg/kg
Remarks: No gross or histopathological evidence of a treatment-related effect. No significant hematologic effects.

Conclusions

Remarks: Triethanolamine is of low toxicity from repeated exposure up to 91 days with a NOAEL of at least 1000 mg/kg.

Data Quality

Reliability (Klimisch): 2B
Remarks: Reliable with restrictions. Basis data provided.

Reference:

CTFA. 1976. Submission of data by CTFA (2-5-55). 91 Day subchronic oral toxicity using triethanolamine. Cited in CIR, 1983.

Other

Repeated Dose Toxicity – Entry 2 of 2

Test Substance

Identity: Triethanolamine
Purity: 99 % reagent grade
Remarks: None

Method

Method/guideline followed: Not stated
Test type: Oral
Year: 1986
GLP: No data
Species: Rat
Strain: Fischer 344
Number and sex: 50 animals/sex/group
Route of administration: Oral (incorporation into the drinking water)
Duration of test: 104 weeks
Dose level: 1 or 2 % triethanolamine in the drinking water.
Mean daily water consumption values in control, low-dose, and high-dose groups of both sexes were 21.7, 20.7 and 21.8 ml/rat in males and 15.4, 18.2 and 17.7 ml/rat in females, respectively.

Control group and treatment: Concurrent control group (50 rats/sex) administered the solvent (water).

Post-exposure observation period: 9 weeks
Methods: Animals were randomly divided into 3 groups, each consisting of 50 rats/sex. Rats were given the test article solutions ad libitum. At week 60 loss of body weight gain and mortality rate increased in the females in the 2 % group. Therefore, the concentration of triethanolamine was reduced by one-half for the females in this group. Triethanolamine solutions were freshly prepared once/week and the amount of solution consumed was measured to calculate the triethanolamine intake. All animals were observed daily and clinical signs and mortality were recorded. Body weights were measured once/week during the first 13 weeks of the study and then once every 4 weeks. At the end of the treatment and observation periods the following organs were evaluated for

histopathological change: brain, spinal cord, peripheral nerves, pituitary, thyroid, thymus, lungs, heart, liver spleen, pancreas, adrenals, kidneys, urinary bladder, salivary glands, tongue, esophagus, stomach, duodenum, jejunum, ileum, cecum, colon, rectum, gonads, accessory genital organs, mammary glands, lymph nodes, skin, musculature, sternum, femur, eyes, and nasal cavity.

Results

Remarks:

None of the treatment groups showed a significant increase in the incidence of any specific tumors over the corresponding control group values. Treatment-related nonneoplastic lesions were observed in the kidneys consisting of mineralization of the renal papilla, nodular hyperplasia of the pelvic mucosa and pyelonephritis with or without papillary necrosis. These findings were observed in a dose-response relationship in males and females from both the low and high dose groups. No other nonneoplastic treatment-related histopathological change was noted in any other organs.

Conclusions

Remarks:

Triethanolamine is not carcinogenic and it does not produce histopathological change to the reproductive organs of either male or female rats when administered in the drinking water at dose levels up to approximately 900 mg/kg.

Data Quality

Reliability (Klimisch): Remarks:

2A
Reliable with restrictions. Acceptable, well-documented publication/study report that meets basic scientific principles.

Reference:

Maekawa, A., H. Onodera, H. Tanigawa, K. Furuta, J. Kanno, C. Matsuoka, T. Ogiu, and Y. Hayashi. 1986. Lack of Carcinogenicity of Triethanolamine in F344 Rats. *J. Toxicol. Environ. Health* 19:345-357.

Other

D. Reproductive Toxicity

No studies have been conducted to specifically evaluate the effect of triethanolamine on reproductive performance. However, based on consideration of the repeat dose toxicity studies of at least 90 days duration, there were no abnormalities noted in the histopathological examination of reproductive organs. This fact, and the lack of effects on development, allow the conclusion that triethanolamine would not be expected to produce toxicity to reproductive performance and fertility. The OECD SIDS Initial Assessment Report (Report) concurs with this opinion. The Report states, “Although there were no studies available on fertility, there were no abnormalities noted in the histopathological examination of reproductive organs (testes and ovaries) in the 90-day oral and dermal toxicity studies. Triethanolamine is not toxic to development or the reproductive system.”

E. Developmental Toxicity

Test Substance

Identity: Triethanolamine
Purity: Purest grade commercially available confirmed by gas chromatography (FID).
Remarks: None

Method

Method/guideline followed: Chernoff-Kavlock teratogenicity screening test
Test type: Oral
GLP: Yes
Species: Mouse
Strain: CD-1
Number and sex: 50 mated females in Phase III
Route of administration: Oral gavage
Duration of test: Through day 3 of post partum.
Dose level: 1125 mg/kg
Exposure period: Exposure of females on days 6-15 of gestation.
Frequency of treatment: The test article was administered daily on days 6-15 of gestation.
Control group and treatment: Yes. Identical dosing regimen treatment group with vehicle.
Methods: This study was conducted in 3 phases. Phases I and II were range finding studies designed as a method to identify the appropriate dose for phase III. Phase I was conducted using non-pregnant animals with administration of the triethanolamine daily for 5 consecutive days. Phase II (4 animals/dose) was conducted using pregnant animals with treatment on gestation 6-15. In phase III the animals were evaluated for the following: maternal body weight, maternal mortality and signs of toxicity, implantation sites, pup counts at birth with mortality and pup weight (recorded at birth and on day 3 postpartum).

Results

As a result of the mortality rate in the phase II pilot study, the dose chosen for phase III was 1125 mg/kg.
NOAEL (NOEL): 1125 mg/kg

Remarks: Oral administration of 1125 mg/kg triethanolamine to pregnant mice did not affect maternal mortality, the number of viable litters, length of gestation, litter size, percent survival of the pups or birth weight or weight gained by the pups.

Data Quality

Reliability
(Klimisch):
Remarks:

1C

Valid with restrictions; Study was conducted according to an established procedure used for screening chemicals for developmental toxicity.

Reference:

Pereira, M., P. Barnwell and W. Bailes. 1987. Screening of Priority Chemicals for Reproductive Hazards. Monoethanolamine, Diethanolamine and Triethanolamine. Environmental Health Research and Testing, Inc. Cincinnati, OH. Project # 200-84-2735.

Other